

**REMARKS/ ARGUMENTS**

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**Rejection under 35 U.S.C. 112, first paragraph**

Applicants have amended Claim 19 to address the substance of the Examiner's rejection and to comply with Applicant's specification. Applicants feel that the claim amendments now make the rejection of independent Claim 19 and dependent Claims 20-25 moot and therefore respectfully request that the Examiner withdraw the rejection and allow Claims 19-25.

**Rejection under 35 U.S.C. 112, second paragraph**

Applicants have amended Claim 19 to address the substance of the Examiner's rejection and to address the subject of Applicant's claimed invention. Applicants feel that the claim amendments now make the rejection of independent Claim 19 and dependent Claims 20-25 moot and therefore respectfully request that the Examiner withdraw the rejection and allow Claims 19-25.

**Rejection under 35 U.S.C. 103(a)**

The Examiner has rejected Claims 19-25 as being unpatentable over Compton US 4,594,902 et al in view of Olson US 3,620,625. Applicants have amended Claim 19 in an effort to clarify Applicant's preferred embodiment. Applicant's claimed invention is directed to an in vitro buccal dissolution test. Neither Compton nor Olson disclose, teach or suggest an in vitro buccal dissolution test. Applicant's specification sufficiently distinguishes buccal dissolution tests from other dissolution tests. One such difference is the sensitivity of the buccal cavity.

One would not look to Olson for an in vitro buccal dissolution test because Olson is concerned with measuring the dissolution rate of a medicament over time not for dissolution of a test sample within a few moments. *Olson, col.2, lns. 24-28.* Olson is continuously passing a dissolution fluid across a test sample in order to achieve the sample's concentration gradient. Olson discloses in the abstract "an apparatus for the

measurement of dissolution rates of solid materials such as tablets, capsules, modules or the like.” In fact, even the illustration shows a whole pill sitting inside of a dissolution chamber. One might argue that Olson teaches away from Applicant’s invention because complete dissolution is necessary to measure the concentration gradient. In Applicant’s invention, complete dissolution is not favored. *Applicant’s page 1*. Applicant is claiming a test which only runs on the order of seconds to minutes, and at the end of the test the sample has not completely dissolved. This is the essence of Applicant’s invention. Complete dissolution is unfavored in the buccal cavity for tastemasking. This is contrary to the teachings of Olson.

Furthermore, Compton discloses a sampling apparatus. Compton discloses no more than a robotic arm for retrieving samples. Compton withdraws samples and in some cases passes them in a filter. One would not look to combine this reference with the teachings of Olson. There is no motivation to combine Compton with the teachings of Olsen to arrive at Applicant’s claimed invention of an in vitro buccal dissolution test. Compton is only directed to sampling. Applicant’s invention relates to an overall test for dissolution.

Thus, Applicants feel that the claim amendments to clarify that the invention is an in vitro **buccal** dissolution test now make the rejection of independent Claim 19 and dependent Claims 20-25 moot and therefore respectfully request that the Examiner withdraw the rejection and allow Claims 19-25.

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CONCLUSION

Applicants have provided a complete listing of the claims and remarks for the Examiner's review. Applicants believe that the pending claims, Claims 19-25, are in condition for allowance and Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Applicants hereby authorize the Commissioner to charge any fees which may be required or credit for overpayment for entry of this Amendment to Deposit Account No. 18-1850.

Respectfully submitted,



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October 16, 2006